



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/579,712

01/03/2007

Edouard Guy Stanley

DVCC-009

5098

24353 7590 05/27/2011  
BOZICEVIC, FIELD & FRANCIS LLP  
1900 UNIVERSITY AVENUE  
SUITE 200  
EAST PALO ALTO, CA 94303

EXAMINER

MONTANARI, DAVID A

ART UNIT

PAPER NUMBER

1632

MAIL DATE

DELIVERY MODE

05/27/2011

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<p align="center"><b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b></p>	<b>Application No.</b> 10/579,712	<b>Applicant(s)</b> STANLEY ET AL.
	<b>Examiner</b> DAVID A. MONTANARI	<b>Art Unit</b> 1632

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 07 February 2011 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☒ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: NONE.  
Claim(s) objected to: NONE.  
Claim(s) rejected: 41-65.  
Claim(s) withdrawn from consideration: 41-65.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_  
13. ☐ Other: \_\_\_\_\_.

/Peter Paras, Jr./  
Supervisory Patent Examiner, Art Unit 1632

Continuation of 11. does NOT place the application in condition for allowance because: Applicant's amendments to the claims raise additional issues of new matter.

Regarding new matter claim 41 is now amended to recite that individual separate hESCs are suspended and then said suspended individually separate hESCs are centrifuged to obtain an aggregation of hESCs. Applicant in their arguments filed on 2/7/2011 stated that Example 1 provides support for these new claim amendments. However a review of Example 1 does not provide support for the new claimed amendments, rather Example 1 is drawn to the aggregation of a suspension of multiple hESCs in individual wells on a 96 well plate. Claim 41 as amended requires that all hESCs that are suspended are individually separate, in other words, every single hESC is by itself in suspension. There is no teaching in the specification that the suspension is made up of individually separate hESCs, nor is there any teaching in the specification that resuspending cultured hESCs will result in their individual separation, i.e. no clumping (see Applicants arguments at pg. 6 on 2/7/2011 regarding the pending 102(b) rejection and addressed below), no 2 or more cells together.

Claims 57 and 65 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons of record in the Final Office Action mailed on 12/7/2010. This is a new matter rejection.

While Applicant has amended claims 57 and 65 to obviate the pending new matter rejection, the non-entry of the amendment results in the new matter rejection being maintained.

Claims 54-65 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record in the Final Office Action mailed on 12/7/2010.

While Applicant has amended claims 54, 56 and 65 to obviate the pending 112, 2<sup>nd</sup> rejection, the non-entry of the amendment results in the 112 2<sup>nd</sup> rejection being maintained.

Claims 41-50 remain rejected under 35 U.S.C. 102(e) as being anticipated by Thomson et al. (US Patent 6,602,711 B1, filed 2/21/2000) for reason of record in the Non-Final Office Action mailed on 2/4/2010, pgs. 3-4 and for reasons of record in the Final Office Action mailed on 12/7/2010.

Applicants argue that Thomson teaches that their hESCs formed clumps in suspension and that the claimed invention is now drawn to individual hESCs that have no clumps at all. While Thomson does teach that their hESCs do form clumps in suspension and not individual hESCs, the pending 102(b) rejection is maintained since Applicant's amendments to the claims have not been entered.

Claims 41 and 50-53 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Thomson et al. (US Patent 6,602,711 B1, filed 2/21/2000) and Kaufman et al. (2001, PNAS, Vol. 98(19), pgs. 10716-10721) for reason of record in the Non-Final Office Action mailed on 2/4/2010, pgs. 4-6 and for reasons of record in the Final Office Action mailed on 12/7/2010.

Applicants argue that the base ref. Thomson teaches that their hESCs formed clumps in suspension and that the claimed invention is now drawn to individual hESCs that have no clumps at all. Applicants continue that Example 1 demonstrates that a cell count was performed on suspended hESCs and that one of skill in the art would readily understand that a desired hESC concentration cannot be achieved if the hESCs are present in aggregates.

However, these arguments are not persuasive. The claimed invention requires that all the hESCs in suspension be individual cells, with no clumping, i.e. 2 or more cells together, however Example 1 states that a sample of the resuspended hESCs was used to get an approximate concentration.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Montanari whose telephone number is (571)272-3108. The examiner can normally be reached on M-Tr 8-6.  
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 1-571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.  
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you

would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

David A. Montanari  
AU 1632